



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,692	07/15/2004	Richard Smith-Carliss	END041182PCT/US	4419
35811 7590 06/25/2008 IP GROUP OF DLA PIPER US LLP ONE LIBERTY PLACE 1650 MARKET ST, SUITE 4900 PHILADELPHIA, PA 19103				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
06/25/2008		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/501,692

**Applicant(s)**

SMITH-CARLISS ET AL.

**Examiner**

DARRYL C. SUTTON

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 25 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 23-26, 28-30 and 33 and 34 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 23-26 and 28-30, 33 and 34 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 1/25/2008. New claims 31 and 32 have been added.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Applicant's arguments filed 1/25/2008 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby maintained. The following rejections and/or objections are either reiterated or newly applied.

#### ***Claim Numbering***

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 31 and 32 have been renumbered 33 and 34. Applicant is advised to renumber claims and provide proper status identifiers in their file.

***Claim Rejections - 35 USC § 103***

Claims 23-26, 28-30, 33 and 34 were rejected under 35 U.S.C. 103(a) as being unpatentable over Angelo et al. (J. of Chromatography B, 1999, Vol. 724).

This rejection is maintained.

In response to the applicant's argument concerning the 103(a) obviousness rejection, claim 23 is drawn to a composition comprised of a compound of formula I or II, i.e. EDDP. All physical properties and activities of the compound, and therefore the composition, are inherent to the structure of the compound. Therefore, it was not necessary for the prior art to teach any of properties or activities of the compound, but to simply disclose or lay the foundation for a composition comprised of the compound. The prior art teaches that EDDP is the major metabolite of methadone. Since methadone induces analgesia and aids in drug deterrence (See applicant's remarks, page 5, last paragraph), one skilled in the art would reasonable expect that similar properties would be found in the main metabolite of methadone. There are R and S stereoisomers of EDDP. One skilled in the art would reasonable expect that one or both of the two forms would have activities and/or properties that are responsible for the analgesic and drug deterring effect of methadone. See In re Adamson, 125 USPQ 233 (CCPA 1960), which sets forth the requirements of patentability with regard to stereoisomers as follows:

- 1) The existence of a racemate is, in and of itself, sufficient to render obvious any individual stereoisomers contained within; no express suggestion of isomer separation is needed. See p. 235, ¶ 1.
- 2) One skilled in the art expects that individual stereoisomers will differ significantly physiological/pharmacologic activity and toxicity, because living systems are chiral and thus

Art Unit: 1612

preferentially process certain stereochemical configurations over others. See p. 234, third full paragraph, and p. 235, fifth full paragraph.

It would then have been obvious to formulate a pharmaceutical composition comprised of either or both forms of EDDP and to take advantage of its/their analgesic and drug deterring effects/activity since this is common practice in the pharmaceutical industry. Ascertaining the amounts of EDDP required for the disclosed activity is a matter of routine experimentation. Where the general conditions of a claim are taught in the art, it is not inventive to discover optimum and workable ranges by routine experimentation. (See MPEP 2144.05, II. Optimization of Ranges). In regards to claims 33 and 34, the claims disclose the exact same composition as that of claim 23, which has been rejected. The disclosure of "blocks an nAChR" and "wherein the nAChR is the  $\alpha 3\beta 4$  receptor" in the claims does not further limit the composition, but instead just recites inherent characteristics of the composition comprised of EDDP. Therefore it is obvious that the compositions of Angelo et al. would have those characteristics.

No claims are allowed.

All rejections are maintained. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

Art Unit: 1612

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/  
Examiner, Art Unit 1612

/Frederick Krass/  
Supervisory Patent Examiner, Art Unit 1612